Paper No. 18

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte OMAR S. KHALIL, SHU-JEN YEH,
XIAOMAO WU, STANISLAW KANTOR,
CHARLES F. HANNA and TZYY-WEN JENG

Appeal No. 2003-1408
Application No. 09/419,461

ON BRIEF

Before KRATZ, JEFFREY T. SMITH and MOORE, ***Administrative Patent Judges***.

JEFFREY T. SMITH, ***Administrative Patent Judge.***

DECISION ON APPEAL

Applicants appeal the decision of the Primary Examiner finally rejecting claims 1 to 6, 8 to 13, 15 to 24, 26 to 31, 33 to 42 and 44 to 52.[1] We have jurisdiction under 35 U.S.C. § 134.

[1] In rendering our decision, we have considered Appellants' arguments presented in the Brief, filed June 24, 2002.

CITED PRIOR ART

As evidence of unpatentability, the Examiner relies on the following references:

Chance et al. (Chance '755)	5,782,755	Jul. 21, 1998
Chance et al. (Chance '821)	5,873,821	Feb. 23, 1999
Mills	5,978,691	Nov. 02, 1999

Laufer, Jan et al. "Effects of temperature on the optical properties of ex vivo human dermis and subdermis," Phys. Med. Biol., vol. 43 (1988), pp. 2479-2489. (Laufer).

THE REJECTIONS[2]

The Examiner has rejected claims 1-3, 6, 8-13, 15-21, 24, 26-31, 33-39, 42 and 44-51 as unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of Mills and Laufer; claims 4-5, 22, 23, 40 and 41 as unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of Mills, Laufer and Chance '755; claim 52 as unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of Mills, Laufer and Chance '821. The Examiner also provisionally rejected claims 1-3, 8-13, 15, 16, 19-21, 26-31, 33, 34, 37-39, 44-46 and 49 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 15, 33, 35 and 36 of copending U.S. Patent Application no. 09/080,470 in view of Laufer. (Answer, pp. 4 and 5).

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[2] The text of the stated rejections appears in the Final rejection, paper no. 7, mailed November 06, 2001.

Rather than reiterate the conflicting viewpoints advanced by the Examiner and Appellants concerning the above-noted rejections, we refer to the Answer and the Brief.

DISCUSSION

We have carefully reviewed the claims, specification and applied prior art, including all of the arguments advanced by both the Examiner and Appellants in support of their respective positions. This review leads us to conclude that the Examiner's rejections are well founded.

Appellants' invention is directed to methods and devices for non-invasively measuring the parameters of a biological sample. According to Appellants, suitable parameters include the presence of a disease condition, progression of a disease state, the presence of and the concentration of an analyte. The method and device of the invention measure light that is reflected, scattered, absorbed or emitted by a biological sample from an average sampling depth. (Brief, p. 3). Claim 1, which is representative of the claimed invention, appears below:[3]

> 1. A method of measuring at least one parameter of a biological sample, said method comprising the steps of:
>
> (a) setting the temperature of said biological sample to a first temperature and allowing said biological sample to equilibrate at said first temperature before

[3] Claim 1 has an error that appears in paragraph (d). Specifically, the term "at" appears twice in the second line.

optical data are collected at said first temperature, said first temperature being within the range of from about 0°C to about 45°C;

(b) performing an optical measurement on said biological sample at said first temperature;

(c) determining at least one optical parameter of said biological sample at said first temperature, said first temperature corresponding to a first depth in said biological sample;

(d) changing said first temperature of said biological sample to at least a second temperature and allowing said biological sample to equilibrate at [at] least said second temperature before optical data are collected at said at least said second temperature, said at least second temperature being within the range of from about 0°C to about 45°C;

(e) performing said optical measurement on said biological sample at said at least second temperature;

(f) determining said at least one optical parameter of said biological sample at least a second temperature, said at least second temperature corresponding to a second depth in said biological sample; and

(g) determining said at least one parameter of said biological sample from the functional relationship of said at least one optical parameter on depth in said biological sample, wherein said biological sample comprises intact human tissue.

Appellants have indicated that all of the claims stand or fall together. (Brief, p. 7).[4]

We will select one claim for each rejection to determine the issues on appeal. 37 CFR

[4] Consequently, Appellants have not provided a grouping of the claims for each ground of rejection.

§ 1.192 (c)(7) and (8) (2001). ***See In re McDaniel,*** 293 F.3d 1379, 1383, 63 USPQ2d 1462, 1465 (Fed. Cir. 2002).

We have carefully reviewed the claims, specification and applied prior art, including all of the arguments advanced by both the Examiner and Appellants in support of their respective positions. This review leads us to conclude that the Examiner's § 103 rejections are well founded. ***See In re Oetiker***, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); ***In re Piasecki,*** 745 F.2d 1468, 1471-1472, 223 USPQ 785, 787-788 (Fed. Cir. 1984). We affirm primarily for the reasons advanced by the Examiner and add the following primarily for emphasis.

The Examiner has rejected claims 1-3, 6, 8-13, 15-21, 24, 26-31, 33-39, 42 and 44-51 as unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of Mills and Laufer. We select claim 1 as representative of the claimed subject matter.

The Examiner has found that Mills describes a device and method for non-invasively measuring the physiological parameters of blood. The method uses the detection of a light signal at a distinct point (wavelength) where the absorbency and extinction of the signal is calculated. The process is repeated at the next chosen wavelength while at the same temperature. Subsequently, the temperature is adjusted to a second predetermined temperature where the process is repeated at the various wavelengths. The Examiner

recognizes that Mills does not discuss the sampling depth. The Examiner cites the Laufer reference for describing the correlation between the sampling temperature and sampling depth. (Final Rejection, pp. 4-5).

Appellants' invention measures the light that is reflected, scattered, absorbed or emitted by a biological sample from an average sampling depth. The article to Laufer describes the influence of temperature on optical properties biological samples. The conclusions of the Laufer article confirm the statement appearing in the specification. Specifically, the specification, page 10, states that "[a]ccording to theories of light propagation in biological samples, light penetration depth in a biological sample depends on both the values of the absorption and scattering coefficients of the biological sample. Changing the temperature of the biological sample causes change in these optical parameters, and hence, change in light penetration depth, up to several hundred micrometers."

Thus, we agree with the Examiner's determination that the subject matter of claim 1 is unpatentable over the combined teachings of Mills and Laufer.

Appellants argue that the claimed invention is distinguished from Mills because "Mills fails to disclose the requirement of allowing a biological sample to equilibrate at a given temperature before optical data are collected at that temperature." (Brief, p. 9). One

with ordinary skill in the art possesses a certain basic level of skill. ***See, e.g., In re Sovish,*** 769 F.2d 738, 743, 226 USPQ 771, 774 (Fed. Cir. 1985). A conclusion of obviousness also may be made based on the common knowledge and common since of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. ***In re Bozek,*** 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969). Here Mills teaches in column 9 that the desired temperature be achieved before the light emitter is used. Moreover, if the sample were not allowed to equilibrate at a given temperature, the results obtained from the measurement would not be comparable to other data. (See Answer, paragraph bridging pages 6 and 7).

Appellants argue that Laufer teaches away from the use of intact tissue as a sample. (Brief, p. 10). Obviousness cannot be rebutted by attacking references individually where the rejection is based upon the teachings of a combination of references. A reference must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole. ***In re Merck & Co.,*** 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986). The Appellants argument does not take into account that Mills, like Laufer, is measuring the influence of temperature on optical properties of the biological sample. The fact that Mills does not describe the invention in terms of depth sampling does not distinguish the invention from the claimed invention.

When the Examiner has met the initial burden of providing references which suggest the claimed invention and the prior art process is substantially the same, the burden is shifted to the Appellants to establish that the invention described by the prior art does not necessarily or inherently possess characteristics attributed to the claimed invention. ***In re Spada,*** 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990); ***In re Best,*** 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Appellants have not present evidence that the process of Mills does not obtain the samples at various depths relative to the temperature employed in the process.

The Examiner added the teachings of Chance '755 to the combination of Mills and Laufer to reject the subject matter of claims 4-5, 22, 23, 40 and 41. The Examiner added the teachings of Chance '821 to the combination of Mills and Laufer to reject the subject matter of claim 52. (Final Rejection, pp. 6-8). In response to both of these rejections, the Appellants argue the Chance references fail to remedy the deficiencies of the combination of Mills and Laufer. (Brief, pp. 11 and 12).

The Examiner has presented factual determinations regarding the suitability of combining the teachings of the Chance references with Mills and Laufer. The Examiner's determinations seem reasonable and are based on the evidence of record. Since Appellants have failed specifically to challenge the factual determinations, we presume that he is in

agreement with the Examiner. Thus, for the reasons presented above regarding claim 1 and the reasons presented by the Examiner we will uphold the rejections.

Based on our consideration of the totality of the record before us, having evaluated the ***prima facie*** case of obviousness in view of Appellants' arguments, we conclude that the subject matter of claims 1 to 6, 8 to 13, 15 to 14, 26 to 31, 33 to 42 and 44 to 52 would have been obvious to a person of ordinary skill in the art from the combined teachings of the cited prior art.

The Examiner also provisionally rejected claims 1-3, 8-13, 15, 16, 19-21, 26-31, 33, 34, 37-39, 44-46 and 49 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 15, 33, 35 and 36 of copending U.S. Patent Application no. 09/080,470 in view of Laufer.

The Appellants do not dispute that the appealed claims are patentably indistinct from the claims of the copending application 09/080,470. Rather, the Appellants' state "Appellants will file a Terminal Disclaimer when claims 13, 15, 33, 35-36 [of] U.S. Serial No. 09/080,470 are issued." (Brief, p. 12). The Appellants, however, do not cite any legal authority for the proposition that the mere offer to file a terminal disclaimer overcomes a rejection based on the judicially created doctrine of obviousness-type double patenting. We therefore uphold with the Examiner's rejection.

CONCLUSION

The rejection of claims 1-3, 6, 8-13, 15-21, 24, 26-31, 33-39, 42 and 44-51 as unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of Mills and Laufer; claims 4-5, 22, 23, 40 and 41 as unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of Mills, Laufer and Chance '755; claim 52 as unpatentable under 35 U.S.C. § 103(a) as obvious over the combination of Mills, Laufer and Chance '821; and the provisionally rejection of claims 1-3, 8-13, 15, 16, 19-21, 26-31, 33, 34, 37-39, 44-46 and 49 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 15, 33, 35 and 36 of copending U.S. Patent Application no. 09/080,470 in view of Laufer are affirmed.

Time for taking action

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

PETER F. KRATZ
Administrative Patent Judge

JEFFREY T. SMITH
Administrative Patent Judge

JAMES T. MOORE
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

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